



#### PATENT AND TRADEMARK OFFICE

#### THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of

On Appeal from Group: 1772

Keith R. D'ALESSIO et al.

Application No.: 09/430,289 Examiner:

S. Hon

Filed: October 29, 1999

Docket No.: 100497.02

For:

POLYMERIC CONTAINERS FOR 1,1-DISUBSTITUTED MONOMER

**COMPOSITIONS** 

## APPEAL BRIEF TRANSMITTAL

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Attached hereto are three (3) copies of our Brief on Appeal in the above-identified application.

Also attached hereto is our Check No. 153221 in the amount of Three Hundred Thirty Dollars (\$330.00) in payment of the Brief fee under 37 C.F.R. 1.17(c). In the event of any underpayment or overpayment, please debit or credit our Deposit Account No. 15-0461 as needed in order to effect proper filing of this Brief.

For the convenience of the Finance Division, two additional copies of this transmittal letter are attached.

Respectfully submitted,

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## THE UNITED STATES PATENT AND TRADEMARK OFFICE

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## **BRIEF ON APPEAL**

Appeal from Group 1700

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#### I. INTRODUCTION

This is an appeal from an Office Action mailed August 20, 2003, finally rejecting claims 1-59 of the above-identified patent application. No claims are allowed. Claim 15 is objected to only for being dependent from a rejected base claim, but is otherwise allowable.

## A. Real Party in Interest

The real party in interest for this appeal and the present application is Closure Medical Corporation, by way of an Assignment recorded in the U.S. Patent and Trademark Office at Reel 10518, Frame 0160.

## B. Statement of Related Appeals and Interferences

There are presently no appeals or interferences, known to Appellant, Appellant's representative, or the Assignee, which will directly affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

### C. Status of Claims

Claims 1-59 are pending. Claim 15 is objected to only for being dependent from a rejected base claim, but is otherwise allowable. Claims 1-14, 16-20, 45-50, 56 and 59 are rejected under 35 U.S.C. §103. Claims 21-44, 51-55 and 57-58 are withdrawn from consideration. Elected claims 1, 45 and 46 are independent. Claims 2-20 and 56 directly or indirectly depend from claim 1; claim 59 depends from claim 45; and claims 47-50 directly or indirectly depend from claim 46.

#### D. Status of Amendments

No Amendment After Final Rejection has been filed. Applicant requested reconsideration in response to the Final Office Action dated August 20, 2003. By an Advisory Action dated December 23, 2003, it was indicated that the rejections were maintained.

## II. THE INVENTION

The claimed invention is directed to containers (including storage vessels, dispensers, applicators, and the like) comprising modified polymeric materials that provide an extended shelf-life for 1,1-disubstituted ethylene monomers for both industrial and medical uses. Page 6, lines 2-5. The Containers comprise a barrier layer that is highly resistant to the effects of permeation by liquids and gases (including vapors such as water vapor that acts as a polymerization initiator), as well as highly resistant to degradation by 1,1-disubstituted ethylene monomers. Page 6, lines 7-11. The containers further provide resistance to degradation of the 1,1-disubstituted ethylene monomers contained therein, where degradation of the composition includes, but is not limited to, premature polymerization (as reflected by viscosity changes) and undesirable changes in reactivity (including increases or decreases in cure time). Page 6, lines 13-17.

In specific embodiments, the invention is directed to a combination including: a container comprising a polymeric resin matrix including at least one post-halogenated polymeric material, and a 1,1-disubstituted ethylene monomer composition contained in said container. Claim 1. In a further embodiment, the invention is directed to a combination including: a container comprising a polymeric resin matrix including at least one functionalized polymeric material, and a 1,1-disubstituted ethylene monomer composition contained in said container. Claim 46.

#### III. THE APPLIED REFERENCES

The applied references are:

U.S. Patent No. 5,785,178 to Kvitrud et al. ("Kvitrud");

U.S. Patent No. 5,693,283 to Fehn ("Fehn");

U.S. Patent No. 3,704,089 to Stehlik ("Stehlik"); and

U.S. Patent No. 4,775,587 to Walles "(Walles").

### IV. ISSUES

The issues on appeal are:

- 1) whether claims 1-9, 16-18, 45-47, 56 and 59 would have been obvious under 35 U.S.C. §103(a) over Kvitrud in view of Fehn;
- 2) whether claims 10-14 and 19-20 would have been obvious under 35 U.S.C. §103(a) over Kvitrud in view of Fehn, and further in view of Stehlik; and
- 3) whether claims 46-50 would have been obvious under 35 U.S.C. §103(a) over Kvitrud in view of Walles.

Because only claims 1 and 46 are separately argued, issue (2) is not addressed in detail below.

## V. GROUPING OF CLAIMS

Each claim of this patent application is separately patentable, and upon issuance of a patent will be entitled to a separate presumption of validity under 35 U.S.C. §282. For convenience in handling of this appeal, the rejected claims will be grouped and argued as follows:

Group I - claims 1-14, 16-20, 45, 56 and 59; and

Group  $\Pi$  - claims 46-50.

Thus, pursuant to 37 C.F.R. §1.192(c)(7), in this Appeal, the rejected claims within each Group will stand or fall together.

## VI. <u>ARGUMENT</u>

The Examiner variously rejects claims 1-14, 16-20, 45-50, 56 and 59 over Kvitrud, combined with one or more of Fehn, Stehlik and Walles. However, in the rejections, the Examiner has consistently improperly applied the law relating to obviousness, and has failed to establish even a <u>prima facie</u> case of obviousness. Proper application of the law and

consideration of the cited reference demonstrates that no <u>prima facie</u> case of obviousness has been shown.

## A. Factual Inquiries to Determine Obviousness/Non-Obviousness

Several basic factual inquiries must be made in order to determine obviousness or non-obviousness of claims of a patent application under 35 U.S.C. §103. These factual inquiries are set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966):

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined.

383 U.S. at 17-18, 148 USPQ at 467.

The specific factual inquiries set forth in <u>Graham</u> have not been considered or properly applied by the Examiner in formulating the rejection of the subject claims. Particularly, the scope and content of the prior art and the level of ordinary skill in the pertinent art were not properly determined and demonstrated and applied to the claimed invention.

In the present case, proper consideration of the factual inquiries demonstrates nonobviousness of the claimed invention. The cited references do not teach or suggest the claimed containers and combination.

B. <u>Containers Including at Least One Post-Halogenated Polymeric Material</u>
(Group I) Are Not Taught or Suggested by the Cited References

Claims 1-9, 16-18, 45-47, 56 and 59 are rejected under 35 U.S.C. §103(a) over Kvitrud in view of Fehn. Claims 10-14 and 19-20 are rejected under 35 U.S.C. §103(a) over Kvitrud in view of Fehn, and further in view of Stehlik. In combination, the cited references Kvitrud, Fehn and Stehlik fail to have rendered obvious the claimed invention, since any teaching of the claimed inventi9n comes only from an improper hindsight consideration of the present application's disclosure.

Independent claim 1, representative of the claims of Group I, is directed to a combination including: a container comprising a polymeric resin matrix including at least one post-halogenated polymeric material, and a 1,1-disubstituted ethylene monomer composition contained in said container. The Examiner argues that Kvitrud teaches all of the limitations of the claimed invention, except for post-halogenation of the inner surface of the container, but that such a teaching is provided by Fehn. Applicants respectfully disagree, and maintain that the claimed invention would not have been obvious over the cited references.

1. <u>Kvitrud Does Not Teach or Suggest Post-Halogenated Materials</u>
Claim 1 specifically requires that the container comprises a polymeric resin matrix,
which includes at least one <u>post-halogenated polymeric material</u>. The claim also specifies
that the container contains a 1,1-disubstituted ethylene monomer composition. Such
containers are not taught or suggested by Kvitrud, and are different from the materials and
containers taught by Kvitrud in terms of their properties and effects.

a. <u>Kvitrud Does Not Teach Post-Halogenated Polymeric Materials</u>
As described by the Examiner in the Office Action, Kvitrud is merely directed to a packaged composition that includes a vial having wall portions defining a chamber and a photocurable material in the chamber. The wall portions transmit less than about 1.0% of actinic radiation, and at least one of the wall portions transmits light having wavelengths in at least part of the visible spectrum. Kvitrud at Abstract.

However, Kvitrud lacks essential elements of the claimed invention. First, as admitted by the Examiner, Kvitrud nowhere teaches or suggests that the container comprises a polymeric resin matrix including at least one <u>post-halogenated</u> polymeric material. In fact, although Kvitrud provides a detailed description of suitable container materials, at col. 3, lines 35-45 and col. 4, lines 25-35. Kvitrud nowhere specifically teaches or suggests the use of <u>halogenated</u> materials at all. That is, Kvitrud nowhere teaches or suggests the use of

container materials that include halogen or other functional species in general, much less that those halogen or other functional species are provided by post-halogenation, as claimed.

## b. <u>Kvitrud Does Not Teach 1,1-Disubstituted Monomers as</u> Container Contents

Second, and contrary to the assertion made by the Examiner, Kvitrud does not teach or suggest that the container is suitable for use with a 1,1-disubstituted ethylene monomer composition, such as a cyanoacrylate composition, as claimed. The Examiner points to col. 1, lines 10-35 as teaching this feature. However, that cited passage is irrelevant to the present rejection.

At col. 1, lines 10-35, Kvitrud discloses that various containers are known in the art for holding various compositions. Kvitrud describes that "squeezable polymeric vials have been long used for various medical and dental preparations ... Commercial and industrial applications include compositions for film developing and other photographic applications, adhesives (such as cyanoacrylates), lubricants and the like." Col. 1, lines 29-36. However, that disclosure is with reference to the prior art, and not to the containers that are the focus of the Kvitrud patent. Kvitrud faults such conventional containers as unacceptable for the photocurable compositions of the reference. Nowhere does Kvitrud disclose, teach or suggest that the containers of the patent could or even should be used for cyanoacrylate adhesives.

Instead, Kvitrud teaches containers specifically designed for photocurable compositions, where such containers address problems in the prior art. Namely the improved containers of Kvitrud are containers that do not allow certain wavelength radiation to enter the container, since such radiation would tend to cure the photocurable composition.

Abstract. Kvitrud nowhere teaches or suggests that photocuring is a concern for cyanoacrylate adhesives, or that the inventive containers of the patent would have any benefit to such cyanoacrylate adhesives.

In response to this argument by Applicants, the Examiner agues in the present Office Action that Kvitrud is directed to improvements over prior art containers, and that cyanoacrylate adhesives would not have been mentioned if they were not suitable for use in the disclosed containers. However, the Examiner's comments ignore the very invention of Kvitrud. Kvitrud is directed to containers specifically suitable for containing materials that are curable upon exposure to light. Such contents are disclosed in particular at col. 1, lines 47-57, which list does not specifically include cyanoacrylate adhesives. The list in Kvitrud at col. 1, lines 47-57 identifies only "certain dental (including orthodontic) adhesives and primers, dental luting cements and other dental preparations such as sealants and crown build-up material," That list is not commensurate with the listing at col. 1, lines 29-36, of contents used in prior art containers, including "eye and ear medications, suntan and sunscreen compositions, body lotions, cosmetics, topical ointments and insect repellents ... compositions for film developing and other photographic applications, adhesives (such as cyanoacrylates), lubricants and the like."

In an effort to overcome this deficiency of Kvitrud, the Examiner cited the <u>Polymer Science Dictionary</u> for showing that cyanoacrylate adhesives are curable by a free radical mechanism. However, that reference does not indicate that cyanoacrylate adhesives are readily curable by visible light. Nor does that reference teach or suggest that the cyanoacrylate adhesives could or should be advantageously contained in the containers of Kvitrud, or that such containment would provide an extended shelf-life to the cyanoacrylate adhesives.

Accordingly, Kvitrud's invention of protecting compositions that are curable by visible light, does not mean that the containers would be readily suitable for containing any contents in general, or cyanoacrylate adhesives in particular. Kvitrud (and the Polymer Science Dictionary) do not teach or suggest that cyanoacrylate adhesives are curable by

visible light, and thus do not teach or suggest the combination of Kvitrud's containers and cyanoacrylate adhesives.

#### c. Conclusion

At most, Kvitrud only teaches that the disclosed containers may be useful for storing compositions that must be protected from exposure to visible light, and in particular to actinic radiation. At most, Kvitrud only arguably suggests this its disclosed containers may be useful for storing cyanoacrylate, since those containers are disclosed as improvements over the prior art. However, even if Kvitrud taught such use, the containers of Kvitrud are not post-halogenated, as claimed.

## 2. Fehn Fails to Overcome the Deficiencies of Kvitrud

To overcome the deficiencies of Kvitrud, and merely by picking and choosing elements of the claimed invention based on the present disclosure, the Examiner cites Fehn.

The Examiner argues that Fehn discloses post-halogenation processing of polymeric container materials, to provide a container that prevents contaminants from entering the container. The Examiner argues that it would have been obvious to combine the cited references to practice the claimed invention. Applicants disagree.

#### a. The Examiner's Premise is Incorrect

Fehn is cited for disclosing a fluorinated layer that provides barrier properties. The Examiner argues that Kvitrud and Fehn are combinable, because it would have been obvious to utilize the barrier layer of Fehn in the container of Kvitrud. The Examiner points out that Fehn discloses the post-halogenation as providing a layer that presents a barrier to contaminants from entering the contained material. However, the Examiner's premise is incorrect, and in fact there would have been no motivation to combine the references in the manner asserted by the Examiner.

The previously submitted Declarations of Keith D'Alessio clearly and unambiguously demonstrates that the claimed container is different from the container that the Examiner asserts would result from a combination of the cited references. Although the previous Declaration addressed different references (Colvin and Maeda), the principles and experimental results provided therein are directly applicable to the present rejection.

In particular, the Examiner argues that the halogenated layer of Fehn provides a barrier layer, superior to any barrier properties provided by the container itself. The Examiner argues that the barrier layer provides protection of the contained materials. The Examiner argues that it would have been obvious to use the post-halogenation process of Fehn to provide additional physical barrier properties to the container of Kvitrud. However, Applicants have demonstrated that this premise -- increased barrier properties as evidenced by a reduced moisture vapor transmission rate -- is in fact incorrect.

Although the previous Declarations addressed different references from Kvitrud and Fehn, the Declarations show that the post-halogenation process does not provide absolute physical barriers to chemical species. The previous Declarations describe that the post-halogenated or functionalized materials of the claimed invention, while providing improved shelf-life to the container and contents, exhibit moisture vapor transmission rates substantially equal to transmission rates of non-halogenated materials. Thus, while the Examiner argues that Fehn provides increased barrier properties beyond that provided by the container matrix itself, the Declaration demonstrates that the process of Fehn does not provide a reduction in the moisture vapor transmission rate.

Thus while the claimed invention provides improved shelf-life and decreased rate of viscosity change to the contained material, the post-halogenated polymer material does not provide an impervious fluorinated surface layer, which the Office Action argues would be provided by Fehn. Accordingly, one of ordinary skill in the art would not have been

motivated to combine the cited references, because there would be no apparent benefit to be obtained once the true result of the combination is known. That is, one of ordinary skill in the art looking at the post-fluorinated layer of Fehn, and realizing that such layer does not provide a barrier to moisture vapor transmission, would not have been motivated to utilize the process of Fehn as a means to improve barrier properties in the container of Kvitrud.

Accordingly, because the Examiner's underlying reasoning for combining the references is incorrect, and because the post-halogenation in fact does not provide the asserted improved barrier properties at least as to moisture vapor transmission, the rejection must be withdrawn.

# b. The Previously Submitted Declarations Apply to the Present Rejection

In response to Applicants' arguments, the Examiner first argues that the previously submitted Declarations are irrelevant, as they do not specifically address Fehn. While Applicants admit that the Declarations do not address Fehn per se, the Declarations do address the issues raised in Fehn and the Office Action. That is, the basis of the Examiner's rejection is the Examiner's assertion that Fehn discloses that post-fluorinated layers provide a barrier to contaminants. This would mean that the Fehn post-fluorinated layers provides a barrier to the transmission of chemical species through the container walls. However, the Declarations clearly establish that post-fluorinated layers do not provide an absolute barrier to all compounds.

Instead, the Declarations establish that post-fluorinated layers do not provide a barrier to at least moisture vapor transmission -- a species that is known in the art to cause polymerization of cyanoacrylate adhesives. See, for example, the <u>Polymer Science Dictionary</u> cited by the Examiner in the Office Action, which discloses that cyanoacrylate adhesive "rapidly polymerizes on exposure to moisture." In fact, the Dictionary cited by the Examiner

makes it clear that of all contaminants or chemical species that must be blocked by a barrier layer (such as in Fehn), moisture vapor transmission is a primary concern. While the fluorinated or post-fluorinated layers of Fehn may be effective to prevent migration of some contaminants in the post-consumer recycled materials used to form part of the container walls, the previous Declarations demonstrate that the post-fluorinated layers are <u>not</u> effective barriers to at least moisture vapor transmission. The Declarations thus demonstrate that Fehn's mere disclosure of barrier properties against some materials, does not mean that the layer is a barrier to all materials, and especially to materials (moisture) that are known to cause premature polymerization of cyanoacrylate adhesives.

Second, the Examiner points out that Fehn is incorporated by reference into the present specification, and that any inoperativeness of Fehn could raise non-enablement issues. Applicants submit that their previous arguments do not raise non-enablement issues. Fehn is cited in the present specification as an exemplary reference for post-fluorinating a material. Although the post-fluorination proves of Fehn does not block moisture vapor transmission, Applicants have discovered that the post-fluorination proves provides benefits to the containers, which provide the desired extended shelf-life to the containers and the contained materials.

Moreover, Fehn uses that post-fluorinated material for a different purpose. Fehn uses the barrier layer to prevent migration of contaminants, arising from the use of recycled polymers materials, into the contained materials. Fehn does not teach that the post-fluorinated layer could be used in a container for containing a 1,1-disubstituted material, as claimed. Applicants' previous (and current) argument is not that the container of Fehn does not work, but merely that the Examiner's premise is incorrect. Applicants cite the previous Declarations as evidence that the Examiner's premise is incorrect, and that the claimed invention provides unexpected results over the prior art.

## c. Kvitrud and Fehn are Non-Analogous Art

Each of Kvitrud and Fehn is directed to non-analogous art from the claimed invention and from each other, and thus there would have been no motivation to combine Kvitrud and Fehn to practice the claimed invention. Prior art references must be "within the field of the inventor's endeavor ... [or] reasonably pertinent to the particular problem with which the inventor was involved." <u>Union Carbide Corp. v. American Can Co.</u>, 724 F.2d 1567, 1572, 220 USPQ 584, 588 (Fed. Cir. 1984).

Kvitrud, discussed above, is directed to a very particular container for containing very particular materials. That is, Kvitrud is directed to a special container that prevents certain wavelength radiation from entering the container, because such radiation would tend to cure a photocurable material contained in the container. Fehn is directed to a container made from post-consumer recycled material, which may have contaminants within the polymer material. To prevent such contaminants from entering the container contents, Fehn applies a protective layer to the inside of the container. Thus, while Kvitrud relates to very specific containers and contents, Fehn relates to container recycling, and a means to prevent contaminants from the container itself from entering the container contents.

In contrast to both Kvitrud and Fehn, the claimed invention is directed to containers for increasing the shelf-life of contained 1,1-disubstituted ethylene monomer compositions, such as cyanoacrylate adhesives. Neither Kvitrud nor Fehn discloses that their containers could or should be used for cyanoacrylate compositions, or that their described improved containers would provide any benefit to such cyanoacrylate compositions. The artisan would not readily recognize these divergent teachings as being applicable to each other, or to the claimed invention. Thus, Kvitrud and Fehn are not within the same field of endeavor as the present invention.

Neither is Kvitrud or Fehn reasonably pertinent to the particular problem with which applicants were involved. The present invention is directed to solving the problems associated with providing containers for increasing the shelf-life of contained 1,1-disubstituted ethylene monomer compositions, such as cyanoacrylate adhesives. Kvitrud is directed to protecting photocurable compositions from visible light and actinic radiation, and Fehn is directed to avoiding contaminants in recycled materials.

In response, the Examiner argues that Kvitrud and Fehn are analogous art, because both relate to the problem of satisfactory containment of volatile polar organic compounds. Applicants disagree. As described above, Kvitrud is specifically directed to containment of substances that are readily curable by visible light, while Fehn is directed to protecting any contained substances from contaminants present in post-consumer recycled plastic materials used to form the container walls. Thus, for example, Kvitrud is directed only to photo-curable compounds, which may or may not be volatile and may or may not be polar organic compounds. However, Fehn is in no way limited to compounds like the photo-curable compounds of Kvitrud. The polar organic compound referred to in Fehn (chloroform) is not photocurable. Moreover, the polar organic compound referred to in Fehn (chloroform) is only one example of materials used in the testing process; Fehn also tested volatile non-polar organic substances (e.g., toluene), non-volatile polar materials (methyl salicylate), and non-volatile non-polar organic materials (10% lindane in toluene). None of these materials are alleged or appear to be photo-curable compounds, such as are the focus of Kvitrud. Accordingly, the references are directed to different containers used to hold different compositions, and which provide different solutions to different problems, and both references are not specifically directed to the problem of satisfactory containment of volatile polar organic compounds as asserted by the Examiner.

Thus, Kvitrud and Fehn are non-analogous art, both to the claimed invention and to each other, and are improperly cited against the instant claims.

## d. There is No Motivation to Combine the Cited References

Furthermore, Kvitrud and Fehn are improperly combined, as there is no motivation for their combination except for in the instant claims.

Two references can not be combined to render obvious the claimed invention where there is no motivation in the references or elsewhere to make the asserted combination. For example, the Federal Circuit held in In re Oetiker that "[t]here must be some reason, suggestion or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination." 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). See also In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination."). That is, it is not enough that a reference may be capable of being modified so as to arrive at a claimed invention. To the contrary, the prior art must have suggested the desirability of such modification to one of ordinary skill in the art at the time the invention was made.

In the present case, there is no motivation to combine Kvitrud and Fehn in the manner asserted by the Examiner. First, neither of the references addresses the problems of the other reference, as described in detail above. Second, Neither reference identifies a problem with its respective container, that could or should be addressed by making the asserted combination. That is, Kvitrud does not teach or suggest that any further improvement is required in the described container, such as to provide the fluorinated barrier layer of Fehn. Kvitrud does not teach that its container is or could be made of post-consumer recycled materials, which would benefit from the treatment of Fehn; instead, Kvitrud is made from very specific materials that are meant to block visible light and actinic radiation. Still further, neither Kvitrud nor Fehn address whether the asserted combination would even be suitable for the objectives of Kvitrud, as neither reference addresses whether such fluorination

treatment would have any adverse impact on the photocurable composition, which is the focus of Kvitrud.

At most, the Examiner alleges that the combination is proper because the Fehn disclosure would be expected to provide improved barrier properties. However, even if improved barrier properties were provided, neither of the references teach or suggest that the containers of Kvitrud require such additional barrier properties, or that the combination would provide an increased shelf-life or a reduced viscosity change rate in the contained 1,1-disubstituted ethylene monomer composition. That is, the references at most teach that the treatment of Fehn would provide reduced moisture vapor transmission through the container wall; however, neither reference teaches or suggests the unexpected result that the shelf-life would be increased and the rate of change of viscosity would decrease.

In response, the Examiner argues in the present Office Action that the absence of any indication in the references relating to any adverse impact of the post-fluorination treatment on contained 1,1-disubstituted monomeric adhesives, implies that there is none. That statement evidences the improper standard of obviousness being applied by the Examiner in the rejections. In order to combine the cited references, the Examiner must cite the motivation to do so, and that motivation must be other than the simple expedient that the limitations appear in Applicants' claims. The motivation for combining the references must include an expectation of success when the combination is made. In the present case, the reactivity of 1,1-disubstituted monomeric adhesives is well known in the art, but neither Kvitrud nor Fehn teach or suggest that the principles of Fehn could be successfully applied to the containment of such reactive materials as 1,1-disubstituted monomeric adhesives as in the claimed invention. Fehn's silence on the issue of motivation and expectation of success, does not substitute for the required presence of these factors.

Accordingly, for at least these reasons, the Office Action has improperly asserted a combination of Kvitrud and Fehn, without any motivation for one of ordinary skill in the art to have made such a combination. The only motivation for the combination derives from Applicants' claimed invention, which is simply an improper hindsight reconstruction of the claimed invention.

## e. One of Ordinary Skill in the Art Would Recognize That the Full Scope of Kvitrud and Fehn Could Not be Combined

In fact, one of ordinary skill in the art would recognize that the full disclosures of Kvitrud and Fehn could not be combined in the manner asserted by the Examiner. Contrary to the legal requirement that there must be some expectation of success in the asserted combination, one of ordinary skill in the art would recognize that embodiments of Kvitrud and Fehn could <u>not</u> be combined, as such a combination would be known to be unsuccessful.

## 1) Some of Kvitrud's Container Materials Can Not be Post-Fluorinated

First, one of ordinary skill in the art would know that at least some of the container materials of Kvitrud could not be successfully post-fluorinated by the methods of Fehn. In particular, Kvitrud discloses suitable container materials to include low density polyethylenes (LDPE), high density polyethylene (HDPE), polyvinyl chloride (PVC), poly(ethylene glycol-co-cyclohexane-1,4-dimethanol terephthalate) (PETG), and poly(ethylene terephthalate) (PET). However, of those five specific suitable materials, at least PET and PETG are not post-fluorinatable, and PVC is post-fluorinatable only to the extent of altering its surface properties to provide better label adhesion. If PET and PETG are attempted to be post-fluorinated, the result is that the resin matrix turns to "mush" and can not be used as a container.

For example, Reference # 1 (which is an excerpt from the Fluoro-Seal internet website) attached as an Appendix to the Request for Reconsideration filed on November 20,

2003, provides a listing of suitable polymers and rubbers that can be post-fluorinated, but the list does not mention PET or PETG. Although PVC does appear in this list, the intent of Fluoro-Seal's process is to increase surface energy in order to increase the adherence of labels and inks to the surface of the bottle, not to increase barrier properties as asserted in Fehn.

## 2) Kvitrud's Pigmented Containers Could Not e Easily Post-Fluorinated

Second, one of ordinary skill in the art would know that the containers of Kvitrud, which can include pigments, could not be easily post-fluorinated by the processes of Fehn. In Kvitrud, the containers are nearly opaque, and such opaque properties can be accomplished with the use of pigments. See Kvitrud at col. 4, lines 15-35. However, it is known in the art that pigmented containers can not be easily post-fluorinated, as would be required in the combination of Kvitrud and Fehn.

For example, Reference # 2 (which is also an excerpt from the Fluoro-Seal internet website) attached as an Appendix to the Request for Reconsideration filed on November 20, 2003, shows that it is known even today to be difficult to implement post-fluorination processing due to the lesser effectiveness of fluorinating pigmented containers. According to Fluoro-Seal, fluorination of pigmented containers may result in slight bleaching, may require alterations in the fluorination process, and requires additional product testing. Fluoro-Seal in fact states that "absolute optimum barrier is always obtained with natural unpigmented resin," i.e., a resin without the pigmentation or other additives required in Kvitrud to provide the desired properties. This further substantiates that it would not have been obvious to combine the fluorination of Fehn to the container systems of Kvitrud.

Accordingly, one of ordinary skill in the art today, much less at the time of the present invention, would not have been motivated to combine the cited references with any expectation of success, and thus the combination is further improper.

3. Stehlik Does Not Overcome the Deficiencies of Kvitrud and Fehn

Claims 10-14 and 19-20, which depend from claim 1, are rejected under 35 U.S.C. §103(a) over Kvitrud in view of Fehn, and further in view of Stehlik. Because these claims are not separately argued from claim 1 (Group I), this rejection is not addressed in detail herein.

Stehlik is cited for various limitations of the dependent claims, and not for the omitted teachings of Kvitrud and Fehn. For all of the reasons set forth above, Kvitrud and Fehn would not have rendered obvious the claimed invention. The cited combination of references is improper, as there is no motivation to have combined the references, and each reference is directed to different and non-analogous art both from each other and from the claimed invention. Further, the asserted basis for the combination -- to provide an impermeable barrier in the inside of the container -- is specifically contrary to the moisture vapor transmission rate experiments that have been provided by Applicants. Because Stehlik does not address any of these deficiencies, the combination of Stehlik with Kvitrud and Fehn cannot overcome the deficiencies of the primary references, and cannot have rendered obvious the claimed invention.

#### 4. Conclusion

For at least these reasons, Kvitrud, in combination with Fehn, and optionally further combined with Stehlik, would not have rendered obvious the claimed invention.

Reconsideration and withdrawal of the rejection are respectfully requested.

C. Containers Including at Least One Functionalized Polymeric Material (Group II) Are Not Taught or Suggested by the Cited References

Claims 46-50 are rejected under 35 U.S.C. §103(a) over Kvitrud in view of Walles.

Applicants respectfully traverse this rejection. In combination, the cited references Kvitrud and Walles fail to have rendered obvious the claimed invention.

Kvitrud is discussed in detail above. Walles is cited for the asserted disclosure that polymeric containers can be functionalized, such as with SO<sub>3</sub> gas, to decrease the permeability of the containers to chemicals. However, regardless of this disclosure, the combination of Kvitrud and Walles suffers from the same deficiency as the combination of Kvitrud and Fehn, discussed above.

In particular, Walles suffers from the same problems as Fehn. The Office Action asserts that Walles discloses that a more impermeable barrier layer can be provided by functionalization with SO<sub>3</sub> gas. However, for the same reasons as described above, Kvitrud and Walles would not have rendered obvious the claimed invention. The cited combination of references is improper, as there is no motivation to have combined the references, and each reference is directed to different and non-analogous art both from each other and from the claimed invention. Nowhere does either reference teach or suggest that further improved barrier properties is required for the container of Kvitrud, or if or how the SO<sub>3</sub> gas of Walles may affect the contained photocurable composition in the container of Kvitrud. Without any clear reason for the combination, and without any clear expectation of success, one of ordinary skill in the art would not have been motivated to make the asserted combination.

Furthermore, the asserted basis for the combination -- to provide an impermeable barrier in the inside of the container -- is specifically contrary to the moisture vapor transmission rate experiments that have been provided by Applicants. Walles is cited for decreasing the chemical permeability through the container. However, Applicants have demonstrated with respect to the post-halogenation treatment that such treatment, and

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likewise the functionalization treatment, does not significantly alter the moisture vapor

transmission rate through the container wall.

Accordingly, any combination of Kvitrud and Walles would be improper, but

nevertheless would still not have rendered obvious the claimed invention. For at least these

reasons, Kvitrud, in combination with Walles, would not have rendered obvious the claimed

invention. Reconsideration and withdrawal of the rejection are respectfully requested.

D. Conclusion

Accordingly, the cited references fails to teach or suggest each and every limitation of

the claimed invention. The claimed invention would thus not have been obvious over the

disclosures of Kvitrud, Fehn, Stehlik and/or Walles.

VII. **CONCLUSION** 

For all of the reasons discussed above, it is respectfully submitted that claims 1-59

define patentable subject matter under 35 U.S.C. §103(a) over the cited reference, and are thus

in condition for allowance. For all of the above reasons, Appellants respectfully request this

Honorable Board to reverse the rejections of claims 1-14, 16-20, 45-50, 56 and 59.

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## **APPENDIX**

#### CLAIMS:

- 1. (Original) A combination including:
- a container comprising a polymeric resin matrix including at least one posthalogenated polymeric material, and
  - a 1,1-disubstituted ethylene monomer composition contained in said container.
- 2. (Original) The combination of claim 1, wherein said post-halogenated polymeric material is present on at least an interior surface of said container.
- 3. (Original) The combination of claim 1, wherein said post-halogenated polymeric material is in direct contact with said 1,1-disubstituted ethylene monomer composition.
- 4. (Original) The combination of claim 1, wherein said polymeric material is selected from the group consisting of a polyolefin and an engineered resin.
- 5. (Original) The combination of claim 4, wherein said polymeric material is high density polyethylene.
- 6. (Original) The combination of claim 4, wherein said polymeric material is linear low density polyethylene.
- 7. (Original) The combination of claim 6, wherein said polymeric material is polyethylene terephthalate.
- 8. (Original) The combination of claim 1, wherein said polymeric material comprises at least one polymer selected from the group consisting of low density polyethylene, linear low density polyethylene, high density polyethylene, cross-linked high density polyethylene, polypropylene, polyethylene terephthalate, polybutylene terephthalate, and oriented polyethylene terephthalate.

- 9. (Original) The combination of claim 1, wherein said container is a laminate and a layer comprising said post-halogenated polymeric material is in direct contact with said 1,1-disubstituted ethylene monomer composition.
- 10. (Original) The combination of claim 1, wherein said combination has a shelf-life of at least about twenty-four months.
- 11. (Original) The combination of claim 1, wherein said combination has a shelf-life of at least about thirty months.
  - 12. (Original) The combination of claim 1, wherein said container is sterilized.
- 13. (Original) The combination of claim 1, wherein said 1,1-disubstituted ethylene monomer composition comprises an alkyl  $\alpha$ -cyanoacrylate adhesive monomer having an alkyl carbon length of at least six carbons.
- 14. (Original) The combination of claim 13, wherein said alkyl  $\alpha$ -cyanoacrylate adhesive monomer is 2-octyl cyanoacrylate.
- 15. (Original) The combination of claim 14, wherein said container comprises:
  a body comprising an interior and an exterior surface, wherein said body comprises a
  post-halogenated high density polyethylene polymer on at least said interior surface,

a dispenser nozzle comprising at least an interior surface, wherein said dispenser nozzle comprises a post-halogenated linear low density polyethylene on said interior surface, and a cap comprising post-halogenated polypropylene.

- 16. (Original) The combination of claim 1, wherein said post-halogenated polymeric material is a post-fluorinated polymeric material.
- 17. (Original) The combination of claim 1, wherein said post-halogenated polymeric material is a post-chlorinated polymeric material.
- 18. (Original) The combination of claim 1, wherein said post-halogenated polymeric material comprises a surface region and a sub-surface region, and wherein a

halogen concentration in said surface region is greater than a halogen concentration in said sub-surface region.

- 19. (Original) The combination of claim 1, said polymeric resin matrix further comprising a halogen-containing acid.
- 20. (Original) The combination of claim 19, wherein said halogen-containing acid is hydrofluoric acid or hydrochloric acid.
- 21. (Withdrawn) A method of manufacturing a polymeric containing a 1,1-disubstituted ethylene monomer, comprising;

providing a container comprising a polymeric material, said container comprising at least an internal surface and an external surface,

halogenating said polymeric material on at least said internal surface of said container, dispensing a 1,1-disubstituted ethylene monomer composition into said container, and optionally sealing said container.

- 22. (Withdrawn) The method of claim 21, wherein said halogenating is performed after molding said polymeric material into a form that is to be the form of the container.
- 23. (Withdrawn) The method of claim 21, wherein said halogenating is performed concurrent with molding said polymeric material into a form that is to be the form of the container.
- 24. (Withdrawn) The method of claim 23, wherein said molding comprises blow-molding a parison using a halogen-containing gas, and said halogen-containing gas also performs said halogenating.
- 25 (Withdrawn) The method of claim 24, wherein residual halogen-containing species from said molding remain captured or dissolved in said container and are not removed from said container prior to said dispensing.

- 26. (Withdrawn) The method of claim 21, wherein said 1,1-disubstituted ethylene monomer is an alkyl  $\alpha$ -cyanoacrylate.
- 27. (Withdrawn) The method of claim 26, wherein said alkyl  $\alpha$ -cyanoacrylate has an alkyl chain length of at least 6 carbons.
- 28. (Withdrawn) The method of claim 27, wherein said alkyl  $\alpha$ -cyanoacrylate has an alkyl chain length of 8-12 carbons.
- 29. (Withdrawn) The method of claim 28, wherein said alkyl chain length is 8 carbons.
- 30. (Withdrawn) The method of claim 21, further comprising sterilizing said 1,1-disubstituted ethylene monomer composition.
- 31. (Withdrawn) The method of claim 21, wherein said halogenating comprises fluorinating said polymeric material on at least said internal surface of said container.
- 32. (Withdrawn) The method of claim 21, wherein said halogenating comprises chlorinating said polymeric material on at least said internal surface of said container.
- 33. (Withdrawn) The method of claim 21, wherein said polymeric material is selected from the group consisting of low density polyethylene, linear low density polyethylene, high density polyethylene, cross-linked high density polyethylene, polypropylene, polyethylene terephthalate, polybutylene terephthalate, and oriented polyethylene terephthalate.
- 34. (Withdrawn) The method of claim 21, wherein residual halogen from said halogenating remains in said polymeric material.
- 35. (Withdrawn) The method of claim 34, wherein said residual halogen forms an acid.
- 36. (Withdrawn) The method of claim 35, wherein said residual acid is selected from the group consisting of hydrofluoric acid and hydrochloric acid.

37. (Withdrawn) A method of storing a 1,1-disubstituted ethylene monomer composition in a container comprising:

providing a container comprising a polymeric resin matrix including at least one post-halogenated polymeric material,

dispensing a 1,1-disubstituted ethylene monomer composition into said container, and

storing said monomer-containing container for more than one year without failure of the container or monomer composition.

- 38. (Withdrawn) The method of claim 37, wherein said storing of said monomer-containing container is for more than twenty-four months without failure of the container or monomer composition.
- 39. (Withdrawn) The method of claim 37, wherein said storing of said monomer-containing container is for more than thirty months without failure of the container or monomer composition.
- 40. (Withdrawn) The method of claim 37, wherein said 1,1-disubstituted ethylene monomer composition comprises an alkyl  $\alpha$ -cyanoacrylate adhesive monomer having an alkyl carbon length of at least six carbons.
- 41. (Withdrawn) The method of claim 37, wherein said 1,1-disubstituted ethylene monomer composition comprises an alkyl  $\alpha$ -cyanoacrylate adhesive monomer having an alkyl carbon length of from two to five carbons.
- 42. (Withdrawn) The method of claim 37, wherein said container is made by a process comprising:

providing a container comprising a polymeric material, said container comprising at least an internal surface and an external surface, and

halogenating said polymeric material on at least said internal surface of said container.

- 43. (Withdrawn) The method of claim 37, further comprising sealing said container between said dispensing step and said storing step.
- 44. (Withdrawn) The method of claim 43, further comprising sterilizing said container after said sealing step.
- 45. (Original) A container containing an adhesive monomer composition, comprising:

a container comprising a polymeric resin matrix including at least one posthalogenated polymeric material, and

an adhesive monomer composition contained in said container.

46. (Original) A combination including:

a container comprising a polymeric resin matrix including at least one functionalized polymeric material, and

- a 1,1-disubstituted ethylene monomer composition contained in said container.
- 47. (Original) The combination according to claim 46, wherein said polymeric material is functionalized with at least one member selected from the group consisting of SO<sub>3</sub>H, CO<sub>2</sub>H, CONR<sub>2</sub>, COX, CO<sub>2</sub>R, SO<sub>2</sub>X, SO<sub>2</sub>NH<sub>2</sub>, SO<sub>2</sub>NR<sub>2</sub>, and mixtures thereof, where R represents a substituted or unsubstituted organic radical and X represents a halogen.
- 48. (Original) The combination according to claim 46, wherein said polymeric material is functionalized with SO<sub>3</sub>H groups.
- 49. (Original) The combination according to claim 46, wherein said polymeric material is functionalized with carboxylic acid groups.
- 50. (Original) The combination according to claim 46, wherein said polymeric material is functionalized with sulfonamide groups.

51 (Withdrawn) A method of manufacturing a polymeric containing a 1,1-disubstituted ethylene monomer, comprising;

providing a container comprising a polymeric material, said container comprising at least an internal surface and an external surface,

functionalizing said polymeric material on at least said internal surface of said container,

dispensing a 1,1-disubstituted ethylene monomer composition into said container, and optionally sealing said container.

- 52. (Withdrawn) The method according to claim 51, wherein said polymeric material is functionalized with at least one member selected from SO<sub>3</sub>H, CO<sub>2</sub>H, CONR<sub>2</sub>, COX, CO<sub>2</sub>R, SO<sub>2</sub>X, SO<sub>2</sub>NH<sub>2</sub>, SO<sub>2</sub>NR<sub>2</sub>, and mixtures thereof, where R represents a substituted or unsubstituted organic radical and X represents a halogen.
- 53. (Withdrawn) The method according to claim 51, wherein said polymeric material is functionalized with SO<sub>3</sub>H groups.
- 54. (Withdrawn) The method according to claim 51, wherein said polymeric material is functionalized with carboxylic acid groups.
- 55. (Withdrawn) The method according to claim 51, wherein said polymeric material is functionalized with sulfonamide groups.
- 56. (Original) The combination of claim 1, wherein said polymeric material comprises polypropylene.
- 57. (Withdrawn) The method of claim 21, wherein said polymeric material comprises polypropylene.
- 58. (Withdrawn) The method of claim 37, wherein said polymeric material comprises polypropylene.

59. (Original) The container of claim 45, wherein said polymeric material comprises polypropylene.